LABCORP DRUG DEVELOPMENT CASE STUDY

Optimizing Protocol Design and Enhancing Patient Enrollment

An emerging biopharmaceutical company was considering development of a pharmacologic agent for treatment of patients with diabetic kidney disease (DKD). The company was designing a Phase II trial in patients who had Type 2 Diabetes, Stage 3 chronic kidney disease (CKD) and macroalbuminuria. They were uncertain about how to balance the selection of the right patients for their trial endpoints with the ability to achieve rapid subject recruitment.

Recognizing the Challenge

The sponsor's initial draft protocol specified an estimated glomerular filtration rate (eGFR) of 30-59 mL/min/1.73m^2 and a urinary albumin-to-creatinine ratio (UACR) greater than or equal to 300 mg/g. Although these protocol entry criteria were consistent with the presence of Stage 3 CKD and microalbuminuria, Labcorp was able to model this and see that rapid recruitment for the Phase II study could be difficult to achieve because of the low prevalence of patients with Type 2 Diabetes who would meet both of these specific criteria for eGFR and UACR.

Mining Patient Data to Determine Protocol Viability

Utilizing the Xcellerate® Protocol Design Tool to mine and analyze the extensive Labcorp de-identified clinical laboratory data which contains more than 30 billion test results across more than 5,000 assays from 150 million de-identified patients, the team searched by ICD codes specific to Type 2 Diabetes, diabetic kidney disease and the desired population's age range.

The rich data from this search enabled the team to evaluate the sponsor's protocol with a focus on the impact of the strict eligibility criteria noted above. With the sponsor's original criteria, the percentage of patients who would qualify for the study was <3% — a figure that put the sponsor's recruitment timeline at risk.

Applying Data-Driven Solutions

- The Xcellerate® Protocol Design Tool, which leverages Labcorp de-identified clinical laboratory data, helped evaluate the protocol feasibility and the overall design of the study
- Database included 1,461,915 patients with Type 2 diabetes who had both an eGFR and a UACR determination
- A minor adjustment in eligibility criteria was forecast to double the eligible patient pool — without impacting study endpoints
- Sponsor gained unique perspective and new insights to help achieve an acceptable screen fail rate

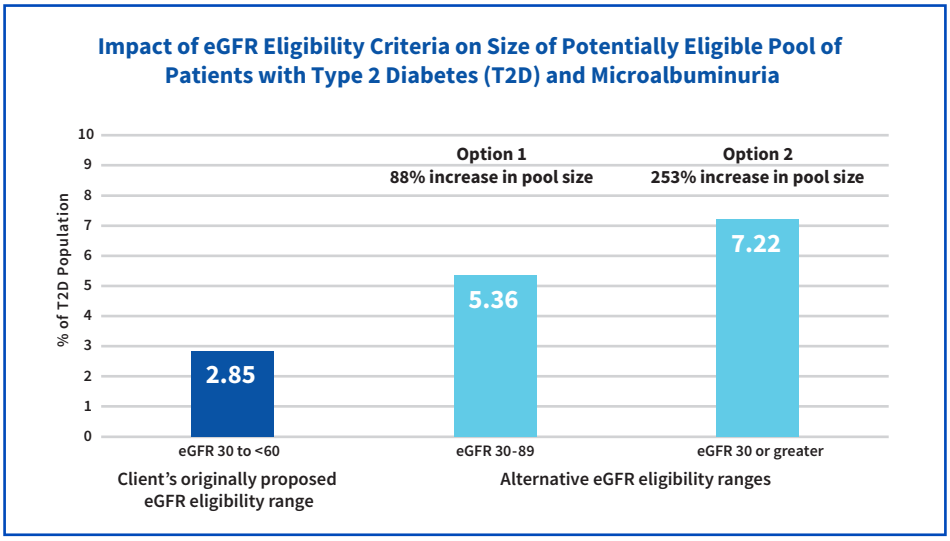
Increased
pool population by
50%
for effective recruitment

labcorp
Drug Development

Minimizing Screen Failure Rates

By modeling a few minor changes to the eGFR and UACR eligibility criteria, the team determined that the pool of potentially eligible patients would more than double, without compromising the objectives of the trial.

As a result, the sponsor adjusted their protocol and was able to substantially reduce the risk of a potentially high screen fail rate. Study investigators were enthusiastic about the revised entry criteria and have been recruiting study participants at a greater than expected rate.



An Expert Explains the Advantage of Up-to-Date Data

Michael D. Cressman, DO, senior medical director and nephrologist at Labcorp, explains why an initial protocol may not be optimal and can benefit from insights mined from Labcorp de-identified clinical laboratory data.

"We often see that sponsors may reuse eligibility criteria from a previous study or just set reasonable eligibility limits without a good rationale. Many sponsors may also rely on data from the National Health and Nutrition Examination Survey or National Kidney Foundation, but those data, while valuable for some purposes, can be several years old.

Given that the standard of care is changing, and new drugs are being introduced, it is critical that sponsors are using the most up-to-date data. Not only is the magnitude of the Labcorp de-identified clinical laboratory data impressive, it contains lab test results that are updated within days.

By applying a current, large clinical laboratory database, we can help sponsors optimize renal entry criteria and derive sample size estimates for these trials — a key feature for more accurately informing key protocol design decisions."

Learn more at drugdevelopment.labcorp.com/Xcellerate

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